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09/806,915	11/13/2001	Christine Nicol	2296.2320	7698

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,915

Applicant(s)

NICOL ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-25, 28-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 22-25, 28-30 and 34+ is/are rejected.
- 7) ☒ Claim(s) 20 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and amendment B filed 08/22/03.

Specification

Applicants failed to address the following issue raised in the previous action and this requirement is repeated below:

This application is a 371 of PCT/GB99/03288 filed 10/06/1999. Applicants are required to present an amendment to the specification instructing the insertion of --- This application is a 371 of PCT/GB99/03288 filed 10/06/1999--- on page 1 of the specification, between the title and line 5.

Claim Rejections - 35 USC § 112

1. Claims 1, 2, 11, 24, 25 and 34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for animal stereotypy, does not reasonably provide enablement for preventing stereotypy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants' argue that stereotypy can be prevented because applicants treated animals from birth in "order to minimize the risk of an animal developing a stereotypy."

2. Applicant's arguments filed 08/22/03 have been fully considered but they are not persuasive. The word applicants used in the argument is "minimize" and minimizing does not rise to the level of preventing/prevention. Specifically, there is no data showing that animals

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have been successfully treated from birth to adulthood and all through life where there is no incidence of stereotypy.

3. The rejection of claims 3-5, 11-23 and 28-30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to the claims.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1 and 8 under 35 U.S.C. 102(b) as being anticipated by Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) is withdrawn because amended claim 1 now recites antacid as part of the composition.

5. The rejection of claims 1 and 8 under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (GB 2 200 027) is withdrawn because amended claim 1 now recites antacid as part of the composition.

Claim Rejections - 35 USC § 103

6. Claims 1, 2, 4 and 6-8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. (GB 2 200 027).

7. Claims 3-6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35).

8. Claims 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of

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Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

9. Claims 11-18, 22, 23, 28-30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) and further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

10. Claims 24 and 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

In summary applicants argue that Winskill is concerned with physically using a Football rather than administration of a fat and fiber diet. Applicants further argue that Pagan cannot be combined with Winskill because Winskill teaches behavioral enrichment devices rather than dietary enrichment. Furthermore, applicants argue that stomach and hind-gut acidity have different chemical basis and are not dependent on each other.

11. Applicants' arguments filed 08/22/03 have been fully considered but they are not persuasive.

Winskill administers to horses a feed of protein, fiber, oil, ash and "timothy hay" and after which observes foraging behavior in the horses and thus the combination of Pagan and Winskill is proper. The combination of Winskill and Johnson is also proper.

Thus the rejections are reiterated below:

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12. Claims 1, 2, 4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. (GB 2 200 027).

Inoue discloses animal feed comprising oil palm fronds that are compressed into compact form for feeding livestock including horses (page 1, lines 17-21). The compact form of the compressed oil palm fronds is a pellet of about 30 mm (3 cm) in length and 15 mm (1.5 cm) in diameter and Inoue states that the size and shape of the pellets may be varied for different types of animals as appropriate (page 2, lines 13-16). According to Inoue, analysis of oil palm leaflets of oil palm fronds yields in percent by weight, 54.3% water, 5.2% crude protein, 2.3% crude fat, 14.3% fibers and 3.7% rough ash, and 19.5 mg/100 g total carotene and 221 mg/100 g Vitamin E (page 5, lines 16-28). Although, Inoue does not refer to water as a pharmaceutically acceptable carrier, the analysis contains water and water is a carrier and is pharmaceutically acceptable. Inoue's animal feed further comprises calcium and/or iron nutritional additives (claims 5 and 6).

Regarding instant claim 8, Inoue is silent or does not disclose the presence of starch in the composition from the oil palm fronds. But the amount of starch is below about 20% and zero is below 20%, which means that the composition in claim 8 does not have to have starch. Future intended use is not critical in a composition claim and the comprising language of claim 1 does not exclude other ingredients.

Inoue clearly teaches the composition of claims 2, 4 and 6 except that Inoue does not refer to the composition as pharmaceutical composition where water is a pharmaceutically acceptable carrier. Regarding claims 4, Inoue's generic fiber encompasses crude fiber and since Inoue discloses cutting the compressed oil palm fronds, the cut fiber encompasses chopped fiber of claims 6 and 7.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising calcium and/or iron nutritional additives and oil palm fronds analyzed to comprise fat and fiber and protein and vitamin E and water and to refer to the composition as pharmaceutical composition since the composition comprises water, which is a pharmaceutically acceptable carrier and since the composition is administered to animals with the expectation of providing healthy stomachs to animals upon administration as disclosed on page 7 line 23 to page 8 line 1 of GB 2 200 027.

13. Claims 3-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). In Winskill, fiber is about 48.5% and fat is about 6.7%. Regarding claim 8, an amount of starch of below 20% reads on no amount or zero amount of starch in the composition such that the Winskill meets the limitations of the claims, where the composition of Winskill does not contain starch.

Claim 1 recites a composition that comprises fat and fiber. Future intended use is not critical in a composition claim. The comprising language in claim 1 does not exclude the presence of protein and ash. Oil is considered to be a fat.

Winskill clearly teaches the composition of the invention except that Winskill teaches 6.7% oil in the composition and the invention recites fat. Regarding claims 4-6, the generic teaching of fiber in Winskill encompasses crude and neutral detergent fiber and does not exclude chopped fiber. Since fat and oil can be used interchangeably by one of ordinary skill in the art,

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it would have been obvious to one of ordinary skill in the art at the time the invention was made to feed horses a composition comprising 24.2% protein, 48.5% fiber, 6.7% fat or oil and 20.6% ash in addition to concentrates and timothy hay according to Winskill since fat and oil are used interchangeably.

14. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber (about 48.5%), 27.5 g oil (about 6.7%) and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Winskill teaches the composition of the instant claims except that Winskill does not teach a feed composition that contains an antacid.

However, Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139). Furthermore, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or

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prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Winskill to treat stereotypic behavior and to incorporate antacid of Johnson or Pagan with the expectation of lowering or reducing the acidity of the hindgut. One having ordinary skill in the art would have been motivated to do this in order to lower the incidence of stereotypic behavior.

15. Claims 11-18, 22, 23, 28-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) and further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

Instant claim 11 is interpreted as a method of treatment or amelioration of stereotypy, the method comprising administering a composition that contains antacid to control stomach pH of an animal for examination purposes. The method is administration.

Johnson discloses that sodium carbonate, an antacid, can be administered to stabled horses to neutralize acidity of hindgut and neutralizing the acidity lowers the incidence of stereotypic behavior (page 39, right column, first paragraph). Johnson recruits 4-10 year old male and female horses in the study where the horses were fed hay and concentrate in alternate week and one of the groups has the feed supplemented with Founderguard (page 140, left column, lines 10-20). The feed also contained crude fiber and crude protein (page 140, left column, lines 21-28). The horses were observed for grasping, wood chewing, cribbing and wind sucking (left column of page 140, lines 42 to the end). Cribbing and wind sucking are stereotypic behaviors.

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The result of the study is that Founderguard led to a reduction in abnormal behavior or stereotypic behavior by reducing acidosis of the hindgut. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that and examiners position is that the horses in Johnson's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15. Regarding claim 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior since the result in Johnson states that administration of Founderguard reduces abnormal behavior by controlling hindgut acidosis. Regarding claim 12, examiner's position is that Johnson's study treated the horses before the stereotypic behavior is permanent or "fixed" as recited in said claim; the examiners position is supported by applicant's admitted prior art on page 7, lines 10-17 that an animal should be treated once the stereotypic behavior is observed before the stereotypy is fixed or permanent since the animal will continue to perform the stereotypic behavior once the behavior is fixed.

Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber (about 48.5%), 27.5 g oil (about 6.7%) and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

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A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by Founderguard for treating stereotypic behavior in animals.

Johnson and Winskill clearly teach the method of the instant claims except that the combined teaching of Johnson and Winskill does not teach administering proton pump inhibitor or histamine type-2 antagonist to control stomach pH, although Johnson suggests that neutralizing acidity of the hindgut with sodium carbonate lowers the incidence of stereotypic behavior.

But, Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use histamine type-2 antagonists or proton pump inhibitor in the composition of Johnson, in place of the sodium carbonate suggested by Johnson, with the expectation that the histamine type-2 antagonists or proton pump inhibitor will reduce or inhibit gastric secretion.

16. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) and Winskill et al. (In Applied Animal Behavior Science, 1966, Vo. 48, pp 25-35) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

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Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber (about 48.5%), 27.5 g oil (about 6.7%) and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat).

Johnson suggests a relationship between pH or acidity of the hindgut and behavioral responses (first and second paragraph, right column, last 2 lines, page 139) and specifically states that neutralizing acidity of the hindgut by administering sodium carbonate lowers the incidence of stereotypic behavior (last four lines of first paragraph, right column, page 139).

A combined teaching of Winskill and Johnson is a method of feeding horses with a feed that comprises fat, fiber, protein, hay and where the feed is supplemented by Founderguard for treating stereotypic behavior in animals and the Founderguard controls hindgut acidosis.

The combined teaching of Winskill and Johnson teaches the method of the invention except that it does not teach treating ulcers.

17. Claims 20 and 21 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20 and 21 directed to including fat and fiber and optionally antacid to the animals diet from birth or including the fiber diet in the feed of the lactating mother are rejected under 35

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USC 112, second paragraph. However, with regards to the claims 20 and 21, the cited prior art is silent on feeding lactating mothers and horses from birth with a diet of fat, fiber and antacid.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner

THURMAN K. PAGE
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